

# Which attributes of LA-ART will affect acceptability?



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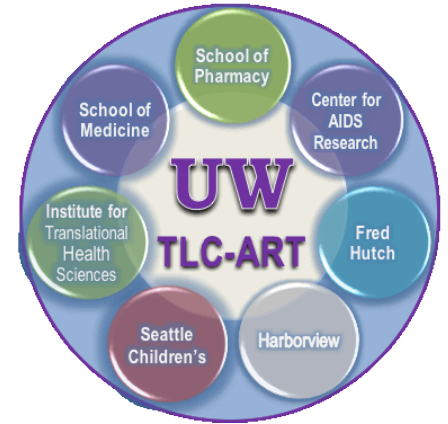
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# Disclosures

- R01 Grant from National Institute of Health
- Discussing the use of drugs that are in the pipeline and not FDA approved

# ***Targeted Long-Acting Combination ART (TLC-ART) Program***

NIH UM1 AI120176 (co-PIs Ho, Collier)



- Goal: To facilitate and guide development of 3 safe, stable, scalable and well-tolerated LA ART formulations for Phase 1 clinical trials
- Innovative aspects:
  - Focus on developing a complete **multidrug** regimen for parenteral delivery
  - Targeting of lymphoid tissues using drug-lipid nano-formulations that can be administered **subcutaneously**

# Acceptability Research (Lead, Simoni)

- Recruitment of providers, PLWH, and parents of infected children from 3 HIV clinics in Seattle and rural southern California
- Qualitative interviews and focus group discussions
  - Notes taken, recordings transcribed
  - Content analysis with coding of salient themes
- Conjoint analysis used to
  - Estimate consumer preferences across discrete attributes
  - Identify factors associated with acceptability

# Qualitative FGD and IDI

- Six FGDs conducted with experienced HIV care providers ( $n=7$ ) and PLWH ( $n=36$ )
- IDIs conducted with parents of children living with HIV ( $n=5$ )
- Providers predicted enthusiasm, especially from patients with adherence challenges, but were concerned about the potential for negative impact on care engagement
- Parents' interest varied according to their child's age and sensitivity to injections

# Qualitative Findings, PLWH

- Concept of long acting injectable ART acceptable despite some concern (“trigger” for IDU)
- Most PLWH preferred clinic administration over self-injection
- Concerns about possible side effects, additional costs, effectiveness compared to oral meds
- Moderate injection site pain more acceptable than multiple injections
- Minimal dosing interval 2 weeks, although 1 month preferred

# Conjoint Analysis Methods

- 56 PLWH aged  $\geq 18$  (median age 52 years, 72% male, 36% Black, 20% Hispanic)
- 8 hypothetical long-acting injectable ART drug profiles varying across 6 dichotomous attributes based on qualitative findings:
  - Location (home vs. clinic)
  - Frequency (qweek vs. q2week)
  - Dose (1 vs. 2 injections)
  - Pain (mild vs. moderate)
  - Injection site reaction (mild vs. moderate)
  - Effectiveness (as good vs. better than pills)
- Participant rated likelihood to use each profile: 0=highly unlikely, 25=somewhat unlikely, 50=neutral, 75=somewhat likely, 100=highly likely

# Conjoint Analysis Results

**Table 1. Conjoint Analysis of Acceptability of Long-Acting Injectable ART among Key populations in the U.S. (N=56)**

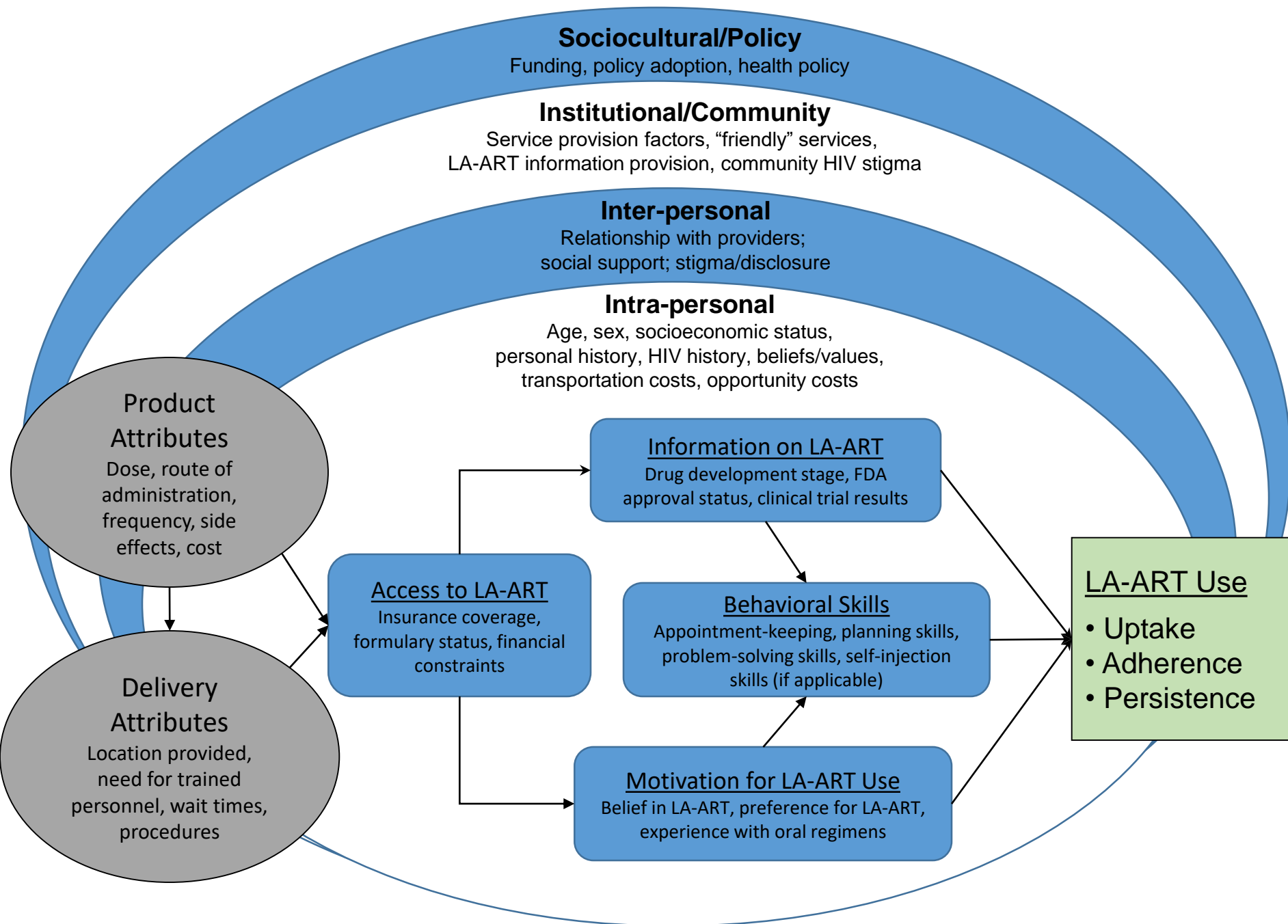
Acceptability Scores (Overall: 57.87)	Attributes [ <i>Preferred underlined in italics</i> ]					
	Location	Frequency	#Sites	Pain	Site reaction	Effectiveness vs pill
68.75	Clinic	<u>2 weeks</u>	Two	<u>Mild</u>	<u>Mild</u>	<u>Better</u>
62.01	<u>Home</u>	<u>2 weeks</u>	<u>One</u>	Moder	Moder	<u>Better</u>
59.38	Clinic	1 week	<u>One</u>	Moder	<u>Mild</u>	<u>Better</u>
57.14	Clinic	1 week	<u>One</u>	<u>Mild</u>	Moder	Same
56.25	Clinic	<u>2 weeks</u>	Two	Moder	Moder	Same
55.80	<u>Home</u>	<u>2 weeks</u>	<u>One</u>	<u>Mild</u>	<u>Mild</u>	Same
55.80	<u>Home</u>	1 week	Two	<u>Mild</u>	Moder	<u>Better</u>
47.78	<u>Home</u>	1 week	Two	Moder	<u>Mild</u>	Same
Impact Score (p-value)	-5.02 (0.42)	5.69 (0.034)	1.45 (0.52)	3.01 (0.15)	0.11 (0.96)	7.25 (0.005)



# Focus Groups in Kenya

- 6 focus groups of PLWH
  - General population men and women, male and female adolescents, female sex workers (FSW), men who have sex with men (MSM)
- Main themes:
  - Poor adherence in the context of high stigma and many side effects – led to high enthusiasm about an injectable option
  - Most had no access to refrigeration
  - Non-disclosure and stigma led to concerns about storage
  - Injections site – NOT stomach
  - Pain not an issue, accustomed to getting injections
  - Getting two shots for one dose not an issue
  - Preferred not to have to come to clinic because of distance, cost, and insensitive treatment
  - Having needles, site reactions feared due to potential stigma

**Figure 1. Factors Associated with the Acceptability of LA-ART Products**



# Questions

- What are the product and delivery attributes that would facilitate uptake, adherence, and persistence on LA-ART regimens among end-user populations?
- How best to measure acceptability as products are in development? Simulated delivery needed?
- How much will end-user views and delivery challenges differ across regions? Across populations?